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APPLICATION NO	). F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,322	09/932,322 08/17/2001		James P. Beltzer	DYX-018.1 US	5654
26161	7590	10/05/2004		EXAMINER	
	ICHARD:	SON PC	CHISM, BILLY D		
225 FRAN BOSTON,	MA 0211	0		ART UNIT	PAPER NUMBER
,				1654	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/932,322	BELTZER ET AL.				
Office Action Summary	Examiner	Art Unit				
	B. Dell Chism	1654				
The MAILING DATE of this communicati Period for Reply	on appears on the cover sheet w	ith the correspondence address				
A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICAT  - Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communicatif the period for reply specified above is less than thirty (30) day If NO period for reply is specified above, the maximum statuty. Failure to reply within the set or extended period for reply will, be Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	FION.  CFR 1.136(a). In no event, however, may a tion.  s, a reply within the statutory minimum of thin period will apply and will expire SIX (6) MOI y statute, cause the application to become Al	reply be timely filed ty (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed or	19 July 2004.					
_	This action is non-final.					
3) Since this application is in condition for a						
Disposition of Claims						
4) ☐ Claim(s) <u>1-38</u> is/are pending in the application 4a) Of the above claim(s) is/are w 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) <u>1-38</u> are subject to restriction a	ithdrawn from consideration.					
Application Papers						
9)☐ The specification is objected to by the Ex	aminer.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection	to the drawing(s) be held in abeyar	ice. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the 11) The oath or declaration is objected to by		• • • • • • • • • • • • • • • • • • • •				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for for a) All b) Some * c) None of:  1. Certified copies of the priority docu 2. Certified copies of the priority docu 3. Copies of the certified copies of the application from the International E * See the attached detailed Office action for	uments have been received. uments have been received in A e priority documents have been Bureau (PCT Rule 17.2(a)).	pplication No received in this National Stage				
Attachment(s)						
1) Notice of References Cited (PTO-892)		Summary (PTO-413)				
<ol> <li>Notice of Draftsperson's Patent Drawing Review (PTO-9-3)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/Paper No(s)/Mail Date</li> </ol>		s)/Mail Date nformal Patent Application (PTO-152) 				

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## **DETAILED ACTION**

Upon further consideration of the claimed inventions, the examiner withdraws the previous restriction, mailed 30 June 2004, and newly restricts the claimed inventions.

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, drawn to a BlyS binding polypeptide, classified in class 514, subclass12, for example.
  - II. Claims 9-10, drawn to a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
  - III. Claims 11-14, drawn to a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
  - IV. Claims 15-23, drawn to a bacteriophage expressing exogenous DNA encodingBlyS binding protein, classified in class 435, subclass 5, for example.
  - V. Claim 24, drawn to method of detecting a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
  - VI. Claims 25 and 28, drawn to a method of purifying a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
  - VII. Claims 26-27, drawn to a BlyS binding polypeptide separation media, classified in class 514, subclass 12, for example.
  - VIII. Claims 29-35 and 38, drawn to polynucleotides and DNA encoding a BlyS binding polypeptide, classified in class 435, subclass 6.

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- IX. Claim 36, drawn to a method of identifying a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
- X. Claim 37, drawn to a BlyS binding polypeptide affinity maturation library, classified in class 514, subclass 12, for example.
- 2. The inventions are independent or distinct, each from the other because:

Groups I and IV are products having different classification and are structurally and functionally independent and having different effects.

The product of Group I is neither made by nor used in the method Group V. Group V methods are for the detection of a BlyS binding polypeptide which wherein if the BlyS binding polypeptide is not present then there will be not detection.

The product of Group I and the method of purifying of Group VI are distinct wherein the product of Group I can be purified by other methods, i.e., various resins, various chromatographies, etc...

Groups I and VII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the product of Group I has separate utility such as immunoassays or molecular weight markers. See MPEP § 806.05(d).

Groups I and VIII are related as product made and apparatus. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and

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materially different apparatus (MPEP § 806.05(g)). In this case the product can be made via posttranslational modification, for example.

Groups I and IX are distinct inventions as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Group I can be used for immunoassays and molecular weight markers, for example.

Groups I and X are independent products that have structural and functional differences with different effects.

Groups II and IV are products having different classification and are structurally and functionally independent and having different effects.

The product of Group II is neither made by nor used in the method Group V. Group V methods are for the detection of a BlyS binding polypeptide which wherein if the BlyS binding polypeptide is not present then there will be not detection.

The product of Group II and the method of purifying of Group VI are distinct wherein the product of Group II can be purified by other methods, i.e., various resins, various chromatographies, etc...

Groups II and VII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the product of Group II has separate utility such as immunoassays or molecular weight markers. See MPEP § 806.05(d).

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Groups II and VIII are related as product made and apparatus. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product can be made via posttranslational modification, for example.

Groups II and IX are distinct inventions as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Group II can be used for immunoassays and molecular weight markers, for example.

Groups II and X are independent products that have structural and functional differences with different effects.

Groups III and IV are products having different classification and are structurally and functionally independent and having different effects.

The product of Group III is neither made by nor used in the method Group V. Group V methods are for the detection of a BlyS binding polypeptide which wherein if the BlyS binding polypeptide is not present then there will be not detection.

The product of Group III and the method of purifying of Group VI are distinct wherein the product of Group III can be purified by other methods, i.e., various resins, various chromatographies, etc...

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Groups III and VII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the product of Group III has separate utility such as immunoassays or molecular weight markers. See MPEP § 806.05(d).

Groups III and VIII are related as product made and apparatus. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product can be made via posttranslational modification, for example.

Groups III and IX are distinct inventions as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Group III can be used for immunoassays and molecular weight markers, for example.

Groups III and X are independent products that have structural and functional differences with different effects.

Group IV is independent of Groups V-VI and IX wherein the product of Group IV is neither made by nor used in the method steps of Groups V-VI and IX.

Group IV is independent of Groups VII and X wherein the products of all groups have structural and functional differences with different effects.

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Groups IV and VIII are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product of Group VIII can be made by PCR methods, for example.

Group V and Groups VI and IX independent method groups with different method steps requiring different components and having different end results.

Group V and Groups VII-VIII and X are independent wherein the methods of Group V neither use nor make the products of Groups VII-VIII and X.

Group VI is independent of Groups VII-X wherein the method of Group VI neither makes nor uses the products of Groups VII-VIII or X. The methods of Groups VI and IX are independent wherein the methods steps require different components with differing effects.

The product of Group VII is independent from Groups VIII-X wherein the product of Groups VII is neither made by nor used in the method steps of Group IX. Group VII is structurally and functionally different from the products of Groups VIII and X with different effects.

Group VIII is independent of Groups IX-X wherein the product of Group VIII is neither made by nor used in the method steps of Group IX, and wherein Group VIII is structurally and functionally different from the product of Groups X, having different effects.

Groups IX and X are independent because the method steps of Group IX neither make nor use the product of Group X.

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3. Claims 1-14 are generic to a plurality of disclosed patentably distinct species comprising those peptides disclosed in claims 1-14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. **Note: claims 1-14 span** 

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three different inventive groups (Groups I, II and III). If Applicants elect any one of Groups

I-III, then Applicants are required to elect a single species that reads on the elected Group.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 4. Because these inventions are distinct or independent for the reasons given above, have acquired a separate status in the art as shown by their different classification, and because the search for one group would not necessarily be inclusive of a search of another group, thus being burdensome to the examiner, restriction for examination purposes as indicated is proper.
- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim

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will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## **Conclusions**

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism

CHRISTOPHER R. TATE PRIMARY EXAMINER